

## REMARKS

Claims 1-36 are presently pending in the case. Claims Claims 10, 23, and 33 are withdrawn from consideration but should be considered in that they depend from an allowable base claim, as discussed below.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

### **Claim rejections under 35 USC 102**

The Examiner rejected claims 1-9, 11-18, and 24-27 under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,692,492 to Bruna et al. (hereinafter Bruna et al). The rejection is traversed.

Bruna et al et al does not anticipate claim 1, for example. To sustain a section 102 rejection, the reference relied upon, must disclose each and every element of the claimed invention. Non-disclosure of a single element of the claim negates anticipation. Claim 1 is to an aerosol drug delivery system comprising, inter alia, a disposable container adapted to contain a drug formulation and an aerosol generator for aerosolizing the drug formulation in response to manual actuation. In contrast, Bruna et al describes an automatic, electronically controlled system of actuation. As discussed in column 8 line 66 through column 9 line 13 and onward, the Bruna et al system detects the patient's inspiratory pressure actuates the device in response thereto. Thus, in contrast to present claim 1, Bruna et al does not disclose an aerosol generator for aerosolizing the drug formulation in response to manual actuation. In Bruna et al the container is locked in an actuated position (column 19 lines 25-38) and the aerosol is electronically actuated. Since Bruna et al does not disclose all positively recited features, a section 102 rejection is precluded. Thus, the Examiner is respectfully requested to reconsider the language of claim 1 and withdraw the rejection thereunder.

Claim 17 is also not anticipated by Bruna et al. Claim 17 is to a method of aerosolizing a drug formulation comprising, inter alia, providing a container having an amount of a drug formulation that is aerosolized in response to manual actuation. Bruna et al does not

disclose a container containing a drug formulation that is aerosolized in response to manual actuation, as discussed above. Thus, Bruna et al does not anticipate claim 17.

Furthermore, claim 28 is not anticipated by Bruna et al. Claim 28 is to an aerosol drug delivery system comprising, inter alia, a control system that controls the opening of a valve such that the valve is only opened when a force is manually applied to depress the canister into the housing and when a dosing condition has been satisfied at which time a locking mechanism is in an active state. Bruna et al does not disclose this feature and does not anticipate the claim.

Claims 2-16 depend from claim 1; claims 18-27 depend from claim 17; and claims 29-33 depend from claim 28. Each of these dependent claims are not anticipated by Bruna et al for at least the same reasons as the claim from which they depend.

#### **Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 34-36 under 35 USC 103(a) as being unpatentable over Bruna et al in view of U.S. Patent 6,024,097 to Von Wielligh (hereinafter Von Wielligh). The rejection is traversed.

Von Wielligh does not disclose the features that Bruna et al is lacking. Accordingly, the combination of references does not render the claims unpatentable.

The Examiner rejected claims 19-22 under 35 USC 103(a) as being unpatentable over Bruna et al in view of U.S. Patent 5,694,919 to Rubsamen et al (hereinafter Rubsamen et al). The rejection is traversed.

Rubsamen et al does not disclose the features that Bruna et al is lacking. Accordingly, the combination of references does not render the claims unpatentable.

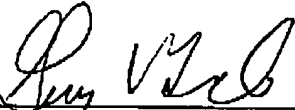
**Conclusion**

The Examiner is respectfully requested to consider and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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